

JAN 24 2000

American Bio Medica Corporation
Rapid Drug Screen 3-Panel Test for Cocaine, THC and Opiates

510(k) Summary

Submitter's Name/Address:

American Bio Medica Corporation
122 Smith Road
Kinderhook, N.Y. 12106

Contact Person:

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Vice President of Product
Development
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Date of Preparation of this Summary:

November 1999

Device Trade or Proprietary Name:

Rapid Drug Screen 3-Panel Test
for CTO

**Device Common/Usual Name or
Classification Name:**

Rapid Drug Screen 3-Panel for
for Cocaine, Marijuana
(THC) (Cannabinoids) and
Opiates

Classification Number/Class:

[no classification number]/Class II

This 510(k) Summary is being submitted in accordance with the requirements of
21 CFR 807.92.

The assigned 510(k) is: 1K 993961

Predicate Device: American Bio Medica "Rapid Drug Screen" 5-Panel Test Kit
with Methamphetamine (K-984525).

Test Description:

All of the assays employed in the Rapid Drug Screen panels are based on the same
principle of highly specific reaction between antigens and antibodies.

Each assay is a one-step, immunoassay in which a specially labeled drug (drug
conjugate) competes with drug which may be present in the sample for the limited
number of binding sites on the antibody. The test device consists of a membrane strip
onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex
is dried at one end of the membrane. In the absence of any drug in the urine sample, the
colloidal gold-antibody complex moves with the urine by capillary action to contact the
immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line
in the "test" area. The formation of a visible line in the test area occurs when the test is
below the cut-off for the drug.

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When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody sites on the colloidal gold-labeled antibody complex. If sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the test area is indicative of a positive result.

A control band (line), comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of drug in the urine, and therefore, should be present in all reactions.

A negative urine will produce two colored bands, and a positive sample will produce only one band.

Intended Use:

The Rapid Drug Screen 3-Panel test for CTO is used for the qualitative detection of the following abused substances in human urine: Cocaine (Benzoyl ecgonine), THC (Cannabinoids) and Opiates. This immunoassay is a simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas chromatography/mass spectrometry (GC/MS).

Performance Characteristics:

This Rapid Drug Screen 3-Panel test will detect drugs of abuse in human urine at the following levels:

Benzoyl ecgonine	300 ng/ml
THC (Cannabinoids)	50 ng/ml
Opiates	300 ng/ml

Reproducibility was evaluated using control urines containing concentrations above and below the stated cut-off. Negative controls were also used. All concentrations were verified by GC/MS. Each sample was tested four times, twice daily, for five days. The results confirmed the reproducibility of the Rapid Drug Screen 3-Panel Test for Cocaine, THC and Opiates.

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Conclusion:

The Rapid Drug Screen 3-Panel for CTO is substantially equivalent to the Rapid Drug Screen 5-Panel with Methamphetamines demonstrated by results obtained in the studies. The three analytes in the kit have been cleared by the 510(k) process (K-984525). There is no evidence of cross-reactivity when the three colloidal gold-antibody complexes are mounted in a common device side-by-side with physical separation of the individual channels.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 24 2000

Mr. Henry Wells
Vice President, Product Development
American Bio Medica Corporation
300 Fairview Avenue
Hudson, New York 12534

Re: K993961
Trade Name: Rapid Drug Screen 3-Panel Test for Cocaine, THC, and Opiates
Regulatory Class: II
Product Code: LDJ, DIO, DJG
Dated: November 15, 1999
Received: November 22, 1999

Dear Mr. Wells:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

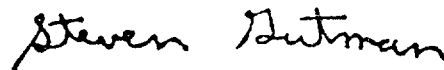
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K 993961

Device Name: Rapid Drug Screen 3-Panel Test for Cocaine, THC, and Opiates

Indications For Use:

"Rapid Drug Screen" 3-Panel Test for Cocaine, THC and Opiates is a one-step, lateral flow immunoassay for the simultaneous detection in urine of three abused drugs at stated detectable limits. (Each assay occupies a separate channel). It is intended for use in the qualitative detection of Cocaine (Benzoyl ecgonine), 300 ng/ml, THC (Cannabinoids), 50 ng/ml) and Opiates, 300 ng/ml.

"Rapid Drug Screen" is intended for professional use. It is not intended for over the counter sale to non-professionals. The assays are easy to perform, but should not be used without proper supervision. These immuno-assays are simplified qualitative screening methods that provide only a preliminary result for use in the need for additional or confirmatory testing, i.e., gas-chromatography/mass spectrometry (GC/MS).

"Rapid Drug Screen" provides only a preliminary analytical test result. A more specific alternate chemical method must be used to obtain a more confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

"Rapid Drug Screen" is not intended for use as a Point of Care test.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K 993961

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐